

**Remarks**

Reconsideration is respectfully requested. Claims 1-20 were pending. Claims 8-20 are withdrawn. Claims 1, 3, 6 and 7 are amended. Claims 4 and 5 have been canceled, and claims 21-23 have been added. Therefore, claims 1-3 and 6-23 are pending.

**Support for Claim Amendments:**

Claim 1: at least at page 4, ll. 20-22; page 5, ll. 6-14; and page 6, ll. 5-9.

Claim 3: at least at page 4, ll. 20-22.

Claims 21 and 22: at least at page 2, ll. 9-16; page 5, ll. 6-14; and page 6, ll. 5-9.

Claim 23: at least at page 2, ll. 14-16, 5, ll. 6-14.

**Priority Claim**

The Examiner alleges that Applicants have not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §§ 119(e), 120, 121, or 365(c). Specifically, prior-filed U.S. Provisional Application No. 60/423,119 ("the '119 provisional application") allegedly does not provide 35 U.S.C. § 112 first paragraph support for the instant application and claims. (Office action, ¶3.) The Examiner also alleges that prior-filed Application Nos. 10/658,125, 10/326,549, and 09/785,695 do not provide 35 U.S.C. § 112 first paragraph support for the instant application and claims. These applications are drawn to a method of isolating GLCN from fungal biomass and do not disclose food product examples comprising at least one baked component and at least one heat-processed component comprising GLCN or NAG. Applicants traverse.

Pending claims of the present application are supported by the disclosure of the '119 provisional application. For example, claim 8 recites a food composition comprising "two components comprising: a baked portion; and a non-baked portion comprising a cartilage supplement selected from the group consisting of GLCN, NAG, and combinations thereof, wherein the non-baked portion is combined with the baked portion." Each element of the claim is supported by the '119 provisional in Example 1 (page 12, ll. 3-23.) Example 1 discloses Rice Krispies® treats containing GLCN or NAG. The treats have two components, *i.e.*, the Rice Krispies® cereal and the melted marshmallow component. The Rice Krispies® cereal is the baked portion. The melted marshmallow component is the non-baked portion. GLCN or NAG was added to the non-baked portion. The baked and non-baked portions were then combined.

Applicants will amend the priority claim, if necessary, at such time as claims in the application are allowed.

**Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 1-7 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Specifically, the Examiner objects to the recitation of "at least about."

Applicants have amended claims 1, 3, 6, and 7 to delete the word "about." Accordingly, Applicants request withdrawal of this rejection of claims 1-7.

**Rejections Under 35 U.S.C. § 103(a)**

Claims 1-7 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over International Application No. WO 01/93847 to Kern and Heisey (Kern) in view of The Ultimate Southern Living Cookbook by Gunter, 1999 (Gunter). The Examiner alleges it would have been

obvious to combine the composition disclosed in Kern with the methods for preparing glazes disclosed in Gunter. Applicants disagree and traverse.

Kern discloses compositions including a chondroprotective agent (e.g., glucosamine, N-acetylglucosamine). In Example 14, Kern discloses a glaze composition that includes, among other ingredients, glucosamine. As admitted by the Examiner, Kern does not teach or suggest heat-processing the glaze or combining it with a baked component.

Gunter discloses several recipes for glazes and fillings wherein the glaze or filling is heated during preparation, and discloses that glazes can be drizzled over a cake, i.e. a baked component. The cited glaze or filling is heated over medium heat to a temperature greater than 212°F. (Page 132.) Gunter does not teach or suggest adding NAG, glucosamine, or any food supplement to a glaze or filling.

#### **Independent Claim 1**

Amended claim 1 recites a food composition comprising "at least two components comprising at least one baked component; and at least one heat-processed component comprising a cartilage supplement selected from the group consisting of GLCN, NAG, and combinations thereof, wherein the heat-processed component can be at any pH, was heated at a temperature from about 160°F to about 180°F, and contains at least 70% of an initial concentration of the cartilage supplement after heat processing."

In rejecting the claims as obvious over the combination of Kern and Gunter, the Examiner cites the medium heated glaze of Gunter and modifies Kern with that teaching. The Examiner states, "One of ordinary skill would reasonably conclude medium heat to be a temperature at which water would not boil (212°F). Therefore, 'medium heat' reasonably

encompasses 180°F." (Office action, ¶12.) The Examiner's assertion that water would not boil at Gunter's "medium heat" is incorrect.

The Gunter "medium heat" exceeds 212°F, as explicitly disclosed by Gunter itself. Gunter's instructions for preparing the Buttermilk Glaze cited by the Examiner explicitly state, "Bring the first 5 ingredients **to a boil** in a Dutch oven over **medium heat**." (Page 132, emphasis added.) The instructions for preparing the cited Lemon-Orange Filling state, "Cook over **medium heat**, stirring constantly, until mixture thickens and **boils**." (Page 132, emphasis added.) The instructions for preparing the cited Bittersweet Glaze state, "[B]ring to a **simmer** over **medium heat**." (Page 132, emphasis added.) The plain meaning of the term "simmer," as disclosed in numerous dictionaries, such *Webster's New World College Dictionary, 4th Ed.*, is "to remain at or just below the boiling point, usually forming tiny bubbles with a low, murmuring sound." ([Http://www.yourdictionary.com/simmer](http://www.yourdictionary.com/simmer).) Thus, combining Kern's glaze composition with the methods disclosed in Gunter would result in heating to temperatures greater than 180°F, as recited in amended claim 1.

Temperatures exceeding 180°F result in significant glucosamine degradation. Table 5 of the present application demonstrates the deleterious effects of excessive heat on the stability of glucosamine. (Specification, page 21.) The percent recovery of glucosamine (GLCNHCl) dropped dramatically in examples where glucosamine-containing compositions were heated at temperatures greater than 180°F. Sugar cookies baked at 375°F for 10 minutes had 50% glucosamine recovery, and corn muffins baked at 400°F for 18 minutes had only 18% glucosamine recovery. However, through extensive testing the Applicants surprisingly discovered that limited heat treatments do not significantly degrade glucosamine. For example, Applicants prepared and tested a Rice Krispies® marshmallow binder, heat-processing it at a

temperature of 165°F for less than 10 minutes. The prepared binder was tested and found to have a glucosamine recovery of greater than 70% (a limitation recited in claim 1).

Accordingly, in the proposed combination of Kern and Gunter, the heat levels of 212 degrees or higher as taught by Gunter would significantly degrade the glucosamine in the Kern glaze resulting in less than the recited 70% retention of claim 1. Consequently, a *prima facie* case of obviousness is not presented and claim 1 is allowable over the art of record.

Additionally, MPEP § 2143.01(V) states, "If [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." The combination of Kern and Gunter renders Kern's glaze unsatisfactory for its intended purpose because the heat levels taught in Gunter would significantly degrade the glucosamine in the Kern glaze. For this reason as well Applicants request withdrawal of the rejection of claim 1.

### **Dependent Claims 2-3 and 6-7**

Claims 2-3 and 6-7 depend from claim 1 and are allowable for at least the reasons set forth above, as well as based on each claim's unique and non-obvious combination of features. For example, claim 4 recites a food composition wherein "the heat-processed component is at a pH of at least 9."

Kern discloses compositions having a first component comprising a chondroprotective agent and a second component comprising a cation source and an edible acid source. Kern discloses that "The second component utilized in the composition is a *critical* component...." (Page 11, ¶1, emphasis added.) Furthermore, Kern discloses that the second component "provides an *acidic matrix* in the composition, which unexpectedly, maintains the stability of the

first component." (Page 11, ¶1, emphasis added.) A *prima facie* case of obviousness is not presented because Kern's compositions would not have a pH of at least 9. In addition, a person of ordinary skill in the art would not be motivated to make the Kern composition to have a pH of at least 9 because, upon reading Kern, it is clear that Kern teaches that it is critical to maintain an acidic composition to stabilize the cartilage supplement therein.

### **New Claims 21-23**

Claim 21 recites a food composition comprising "at least two components comprising at least one baked component; and at least one heat-processed component comprising a cartilage supplement selected from the group consisting of GLCN, NAG, and combinations thereof, wherein the heat-processed component does not require pH adjustment, was heated at a temperature of about 160°F to about 180°F, and contains at least 70% of an initial concentration of the cartilage supplement after heat processing." Support for this claim is found in the specification, *e.g.*, at page 2, ll. 9-12, and page 6, ll. 5-9. Claim 22 is similar to claim 21 and has the same basis in the specification thereof.

As previously discussed in relation to claim 1, Kern discloses a glaze composition, but does not teach or suggest heating the glaze. The Examiner's proposed modification of Kern with the heating taught by Gunter results in a composition (1) wherein the non-baked component could not meet the recited 70% retention of the cartilage supplement since the proposed combination would have been prepared by a method having a temperature that has been shown to cause significant degradation of the same, and (2) because the proposed combination results in a temperature preparation that far exceeds the temperature ranges recited in claims 21 and 22.

Furthermore, Kern discloses compositions including a chondroprotective agent and a second acidic component that is *critical* for maintaining stability of the chondroprotective agent. (Page 11, ¶1.) Addition of the acidic component ensures that an acidic matrix is maintained within the composition and inherently adjusts the pH of the composition – this is in direct contradiction to the recited composition of claims 21 and 22. Thus, claims 21 and 22 are not obvious in view of the combination of Kern and Gunter.


Claim 23 recites a food composition comprising "at least two components comprising at least one baked component; and at least one heat-processed component comprising glucosamine, wherein the heat-processed component contains at least 70% of an initial concentration of glucosamine after heat processing." Support for this claim is found in the specification, *e.g.*, at page 2, ll. 14-16, and page 5, ll. 6-14. As previously discussed in relation to claim 1, the combination of Kern and Gunter would not result in a heat-processed component containing at least 70% of an initial concentration of glucosamine due to the excessive heat levels taught by Gunter. Accordingly, claim 23 is not obvious in view of Kern and Gunter.

Respectfully submitted,

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